U.S. Department of Justice
Drug Enforcement Administration

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Springfield, Virginia 22152

Confidential and Subject to Federal Rule of Evidence 408

DATE: November 4, 2014

Via Federal Express and Electronic Mail

Geoffrey Hobart, Esq.
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004

Re: Registration Consequences for McKesson Corporation for Violations of the Controlled Substances Act

Dear Mr. Hobart:

Thank you for meeting with us on October 27, 2014 in Denver regarding DEA registrants owned and operated by McKesson Corporation ("McKesson") and the potential administrative consequences for those registrants as a result of McKesson's failure to "maintain[] effective controls against diversion of particular controlled substances," 21 U.S.C. §§ 823(b)(1), and to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). As you know, DEA has been investigating McKesson's Distribution Center located at 14500 East 39th Ave., Aurora, Colorado 80011 (DEA Certificate of Registration ("COR") PM0018425) ("McKesson Aurora") for violations of these laws. The evidence uncovered in the McKesson Aurora investigation was described in detail in the August 13, 2014, letter you received from the U.S. Attorney for the District of Colorado about the civil penalties that that office may seek. Because you are aware that our office may bring an administrative action to revoke McKesson Aurora's DEA COR based on that same evidence, you asked for meetings with us to discuss DEA's participation in a potential global settlement — a resolution to include a release of both civil claims and administrative claims for registration consequences against McKesson related to its conduct.

PLAINTIFFS TRIAL EXHIBIT
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After our meeting, it is our understanding that your client would be willing to accept (1) a voluntary surrender of McKesson Aurora's DEA COR and a commitment not to reapply for a new COR for that facility for two years from the date of the execution of the global settlement and (2) a surrender of one other DEA COR for a distribution center with a commitment not to reapply for one year. You did not identify the second specific distribution center's registration to be surrendered.

DEA recognizes that our meeting in Denver was the beginning of the discussion, not the end. We also understand that registration consequences may have an impact on your client's distribution network. In this latter respect, we appreciate the participation by Donald Walker, who helped to explain to us the significance of these concessions and the relative impact that registration consequences might have on various different distribution centers that are encompassed by our investigation.

That having been said, we remain concerned that McKesson fails to appreciate the serious and systemic nature of the CSA-related problems that DEA has observed in its several investigations into your client's operations. As we conveyed to your client in Denver, we believe that any potential resolution of administrative actions against McKesson registrants should be driven primarily by the evidence in this case — evidence DEA considers to be serious. It will not necessarily involve registration consequences for those McKesson distribution centers less critical to the overall functioning of McKesson's distribution network. Although this would clearly be preferable from the perspective of your client's shareholders, the financial impact of the surrender of DEA CORs on McKesson is not DEA's overriding concern. The loss of business that McKesson may experience as a result of surrendering DEA CORs is a justified and appropriate consequence that is consistent with the public interest. Among other reasons, we hope that McKesson distribution centers that maintain DEA registrations after a global settlement will take their responsibilities under federal law more seriously than they did after the 2008 settlement.

In order to release all McKesson-owned DEA registrants from administrative liability as you have requested, the agreed-upon registration consequences must reflect not only the gravity of the offenses, but nationwide scope of McKesson's failure to report suspicious orders and to maintain effective controls against diversion. In service of the parties' discussions, we thought it may benefit your client to explain the sort of evidence that DEA has discovered and may present in administrative proceedings. This is, of course, not intended to be an exhaustive survey of the evidence DEA or DOJ may rely upon in proceedings against McKesson.

As we have discussed previously, McKesson Aurora lacked a functional suspicious order reporting system for approximately five years. McKesson Aurora reported a total of 16 orders as suspicious (in one batch, occurring in one quarter, related to one recently terminated pharmacy) while it processed a total of 1.6 million orders for controlled substances from 2008 through 2012. This, alone, demonstrates that it was not operating with any functional "system to disclose . . . suspicious orders of controlled substances" to DEA. *See* 21 CFR 1301.74(b). And the fact that this occurred *after* McKesson had entered into a settlement agreement with the Department of Justice and DEA in which McKesson committed to report suspicious orders makes the ensuing five-year silence particularly egregious. As outlined in more detail in the letter you received from the U.S. Attorney's office, it is apparent that McKesson Aurora avoided filing of suspicious order reports by giving short shrift to supposed due diligence efforts and manipulating the monthly thresholds that were the cornerstone of McKesson's compliance program.

Like its Colorado counterpart, McKesson's Distribution Center at 38220 Plymouth, RD, Livonia, MI, DEA COR PM0030849 ("McKesson Livonia") reported no suspicious orders for approximately five years after McKesson's settlement with DOJ. McKesson Livonia remained silent even as it supplied 26 pharmacies that were utilized in a drug trafficking conspiracy that has since resulted in the criminal conviction of the owner of these pharmacies, Babubhai Patel, and dozens of other participants. McKesson's "system to disclose . . . suspicious orders of controlled substances," 21 CFR 1301.74(b), identified none even when one of Patel's pharmacies, Preferred Care Pharmacy, for example, went from ordering less than 4,000 dosage units of hydrocodone products in March and April of 2010 to regularly ordering 16,000 dosage units a month in August 2010, to regularly ordering more than 20,000 dosage units a month in 2011. The threshold that was supposed to trigger review for suspicious ordering by McKesson Livonia instead prompted efforts by McKesson Livonia to reset this threshold to enable ever increasing hydrocodone sales. Worse, hydrocodone products constituted more than 70% of the controlled substances that Preferred Care Pharmacy was ordering — an obvious indicia of diversion that was, unfortunately, quite common among the Patel pharmacies and readily apparent to McKesson Livonia. Of course, McKesson Livonia's failure to detect suspicious orders was not confined to pharmacies in the Patel criminal conspiracy. McKesson Livonia saw orders of hydrocodone from People's Pharmacy in Detroit rise from less than 10,000 dosage units a month when it first came online in July 2010 to double and then triple so that it was regularly ordering more than 30,000 dosage units a month by the end of the year. McKesson Livonia's only action was to regularly raise thresholds to permit this, offering little more than "due to increase in business" as the reason why the thresholds needed to be doubled and tripled. While McKesson Livonia was doing so, Michigan Pharmacy Board inspectors (who subsequently suspended the pharmacist's license) were able to watch from the parking lot as "drivers" would drop off multiple "patients" to pick up prescriptions — diversion so obvious the pharmacist readily admitted misconduct to investigators when confronted.

McKesson's systemic failures were also evident at its distribution center at 3000 Kenskill Avenue, Washington Court House, Ohio, DEA COR RM0220688 ("McKesson WCH"). Here, again, McKesson did not report any orders as suspicious for years after the 2008 settlement with DOJ and DEA. When DEA began to investigate this silence, McKesson's Regional Director of Regulatory Affairs told DEA investigators that he did not know what a suspicious order was and protested that DEA had not adequately defined the term. McKesson's inability to instill a culture of compliance — even within its compliance operations — may explain why McKesson WCH did not report anything suspicious about Community Drug of Manchester, Kentucky — a pharmacy located in a town of less than 1,000 adult residents — ordering 20,000 to almost 50,000 dosage units of oxycodone products on a monthly basis in 2011. Indeed, McKesson WCH only took action to reduce this pharmacy's threshold for oxycodone products after receiving a tip from the state pharmacy board that it was under investigation. Even after McKesson WCH was aware that this pharmacy was under investigation, it continued to supply it with controlled substances while apologizing for having to reduce thresholds and promising to "bump up" those thresholds as soon as they could justify doing so. In September 2012, federal and state law enforcement officers executed a search warrant on Community Drug as part of an investigation that ultimately resulted in the criminal conviction of the lead pharmacist and his wife. Days *after* that search warrant was executed (and covered by local television news outlets), McKesson WCH contacted Community Drug telling it that it would be seeking a "pretty sizable increase" in the oxycodone and hydrocodone thresholds for this store. In that same

month, McKesson WCH's blind eye for suspicious ordering was again apparent when it set a monthly threshold of 112,000 dosage units of hydrocodone products for Family Discount Pharmacy — one of three pharmacies located in Mount Gay, West Virginia, with an adult population of less than 1,500. Even when Family Discount Pharmacy exceeded that extraordinary threshold — making this rural pharmacy one of the top purchasers of hydrocodone in the state — no orders were reported as suspicious. In March 2014, McKesson's Regional Director of Regulatory Affairs visited this pharmacy in person and approved continuing to ship controlled substances this customer — a decision that was contradicted weeks later when a new employee conducted the same on-site review.

McKesson's system to detect suspicious orders also fell short at the distribution center at 1515 Kendrick Lane, Lakeland, FL 33805 (DEA COR PM0000771) ("McKesson Lakeland"). Once again, in derogation of its responsibilities under the CSA and the 2008 MOA, McKesson Lakeland failed to report and suspicious orders to DEA for a five-year period. Further, as an example, McKesson Lakeland's conduct with regard to two of its pharmacy customers, establishes its lack of maintenance of effective controls against diversion. While investigating a threshold increase request by Oviedo Healthmart Pharmacy in January 2010, McKesson Lakeland was aware that their oxycodone purchases (before the requested threshold increased) were high (36% of all controlled substance purchased from McKesson Lakeland), and acknowledged that for a pharmacy that conducted less than $50,000 in sales per month, Oviedo's purchase of 11,000 in dosage units of oxycodone "could be considered high." Nevertheless, McKesson Lakeland not only failed to report any orders placed by Oviedo as suspicious, but continued to distribute controlled substances to this pharmacy customer. In addition, McKesson Lakeland's treatment of another pharmacy customer, Modern Pharmacy, highlights the improper influence McKesson's sales personnel had on compliance decisions. In May 2012 and again in September 2012, emails show that McKesson Lakeland advanced sales over compliance when faced with potential compliance issues. For example, when the Director of Operations for McKesson Lakeland proposed reducing Modern Pharmacy's oxycodone 30mg threshold from 8,000 to 5,000 dosage units due to the pharmacy's high ratio of oxycodone to oxycodone 30mg (over 50%), the response from McKesson's sales representative was "We need to discuss before any changes are made. This is a big win for us and a high HIV pharmacy. We knew this during negotiations." According to McKesson Lakeland documents, no changes were made to this threshold, thus indicating that McKesson prioritized sales over adherence to its regulatory obligations.

McKesson also remained silent about suspicious orders received by its distribution center at 9 Aegean Dr. Methuen, MA 01844 (DEA COR PM0020850) ("McKesson Methuen"). As with other distribution centers McKesson operated, McKesson failed to report any suspicious orders from May 2008 through November 2013, though it sold increasing amounts of oxycodone during the same time period, with little to no investigation. Specifically, McKesson Methuen sold approximately 292,000 dosage units of oxycodone to Alexander's Pharmacy ("Alexander's"), a pharmacy located in Dracut, Massachusetts, a city with a population of 29,457 residents. By supplying Alexander's an inordinate amount of oxycodone, McKesson Methuen enabled Alexander's in total to purchase over half (55%) of the total oxycodone purchases by pharmacies in this particular town. A review of McKesson Methuen's due diligence file procured through a DEA-issued subpoena revealed that McKesson Methuen performed no Level 1 reviews prior to its distribution of oxycodone to this pharmacy, but instead continued to sell the pharmacy increasing amounts of oxycodone. Similarly, the same

distribution center also sold inordinate amounts of oxycodone to Betro Pharmacy ("Betro"), a pharmacy located in a small town, Walpole, Massachusetts, population 5,918 residents. In 2012, McKesson Methuen supplied approximately 190,000 dosage units of oxycodone to Betro, though four other pharmacies existed in the town. In total, by supplying this pharmacy, McKesson Methuen enabled this particular pharmacy to supply 50% of the town's oxycodone in 2012. Additionally, as with other pharmacies DEA has identified, McKesson Methuen allowed sales decisions to dictate the scope of McKesson Methuen's sales to the pharmacy. In a Threshold Change Request dated September 16, 2009, shortly after McKesson Methuen procured the pharmacy as a customer, the pharmacy requested an increase in its threshold for oxycodone, lorazepam, and clonazepam. Though Betro was not approaching the established threshold for the hydrocodone, the base code underlying the request, McKesson Methuen personnel justified the threshold increase as "High volume account that came primary last month from ABC [Amerisource Bergen]. Usage must be updated." Based on the documentation provided, McKesson did nothing to further investigate the pharmacy's request for an increase, but instead relied on the fact that the pharmacy was recently obtained from a competitor, Amerisource Bergen.

As noted above, the above examples are illustrative, not exhaustive. They are meant to illustrate what we mean when we say that we will be driven by the evidence that we could present in administrative proceedings against these registrants.[1] We have attempted to highlight this evidence in the hopes that you and your client can fully understand why DEA believes that the failings at McKesson were as systemic as they were serious.

To be clear, DEA is not unmindful of the financial and operational consequences of taking a particular McKesson facility offline may be. At the same time, however, our principal goal in this aspect of any global settlement is to reach a justified and appropriate consequence for the misconduct DEA has observed, including the fact that McKesson compliance efforts in the wake of the 2008 MOA were demonstrably inadequate. From the standpoint of registration consequences, DEA continues to be open to a settlement that is consistent both with the nature and extent of the misconduct observed, as well as DEA's need to safeguard the public interest. In terms of the public interest, we remain mindful of the need to ensure unimpeded access to controlled substances by patients. DEA similarly has no intention or desire to negatively affect the distribution of controlled substances for other legitimate medical, scientific, and industrial purposes.

We remain open to any proposal that your client might wish to make that adequately reflects DEA's dual goals of an reaching an appropriate sanction for McKesson while at the same time ensuring legitimate patients and entities will continue to have uninterrupted access to controlled substances. But as we emphasized to you and your client last week, these discussions

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[1] As you know, DEA has a number of additional ongoing investigations into various McKesson distribution centers, including in 3775 Seaport Blvd., West Sacramento, CA 95691 (DEA COR PM0021535), 1995 McKesson St., Suite 101, Aurora, IL 60502 (DEA COR RM0380484), 7009 South 108 Street, La Vista, NE 68128 (DEA COR PM0038693), 400 Delran Parkway, Delran, NJ (DEA COR RM0173055), 10504 McKesson Drive, Ruther Glen, VA 22546 (DEA COR RM0424363), and 3003 Airport Rd., Lacrosse, WI 54603 (DEA COR RM0220537). For purposes of this correspondence, DEA has not attempted to address the evidence related to these locations, as the evidence that DEA discussed in this letter is more than sufficient to demonstrate the systemic nature of McKesson's compliance deficiencies.

cannot continue in perpetuity. All parties have recognized that our ability to continue these discussions depends on the progress we make and the pace at which we make it. We hope you take this letter in the constructive spirit in which it is intended and we look forward to continuing discussions with you.

Sincerely,

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cc: C. Lee Reeves, Section Chief, Diversion & Regulatory Section, Office of Chief Counsel